3.2 Medical Requirements Overview

TABLE 3.2: MEDICAL REQUIREMENTS OVERVIEW

MEDB# and Title:	MEDB 4.1 Cycle Ergometer Test/Aerobic Functional Capacity
Sponsor:	Medical Operations
Discipline:	Bone, Muscle & Exercise, Occupational Health Branch
Category:	Medical Requirements (MR)
References:	International Space Station Medical Operations Requirements Document (ISS MORD), SSP 50260 Medical Evaluation Documents (MED) Volume B Section 4.1 and 4.3
Purpose/Objectives:	To assess cardiovascular status and aerobic fitness. The testing shall be performed on an annual basis for all astronauts on active flight status. Once a crewmember is assigned a specific mission, testing will be performed according to the single flow to launch schedule contained herein. The annual testing documents the astronaut maintains an acceptable cardiovascular training status and has no clinically significant cardiac abnormalities. The pre-, in- and postflight testing provides data to set or adjust specific exercise prescriptions for each individual's use on board ISS and during recovery from long duration flight. The data from these assessments also provide group data for analyzing countermeasures and rehabilitative programs.
Measurement Parameters:	ECG, heart rate, oxygen consumption to maximum (VO_2 max). Blood pressure and ratings of exertion are to be monitored during testing. ECG will be used to assess the presence or absence of cardiac dysrhythmia and electrical evidence of myocardial ischemia.
Deliverables:	Assessment of VO_2max by Exercise Physiologists and ECG interpretation by Cardiologist.
Flight Duration:	≥ 30 days for flight, annual requirement otherwise.
Number of Flights:	Every ISS Expedition
Number and Type of Crew Members Required:	All U.S. crewmembers. Participation of IP crew members in these specific test protocols performed by US personnel will be negotiated between the US and respective IP's Medical Operations representatives.
Other Flight Characteristics:	None

3.3 Preflight Training

TABLE 3.3: PREFLIGHT TRAINING

Preflight Training Activity

Description:

Countermeasures Systems CEVIS Operations (CMS OPS): This lesson introduces crewmembers to some of the Countermeasures Systems (CMS) hardware and software. It includes the Heart Rate Monitor (HRM), the Cycle Ergometer with Vibration Isolation System (CEVIS), and the Countermeasures Software (CMSS) located on Space Station Computers (SSC) which is used for data storage, data transmission and data retrieval. The lesson focuses on the purpose and operations of CMS hardware and software, incorporating procedure use throughout.

Countermeasures Systems Periodic Fitness Evaluation (PFE) Operations (CMS PFE Ops): This lesson covers the Periodic Fitness Evaluation (PFE) procedure that is performed every 30 days during flight. Crewmembers are expected to work through the procedures necessary that will integrate using the Cycle Ergometer with Vibration Isolation System (CEVIS), the Station Support Computer (SSC), and the Blood Pressure/Electrocardiograph (BP/ECG). Some review of the CEVIS and HRM operations are also included in the lesson.

Integrated Physical Fitness Assessment Training: This lesson provides further training on the test hardware and familiarizes the crewmembers with the testing protocol. This training is the responsibility of the Exercise Physiology Laboratory (EXL) group. The focus is to know the purpose and the components used, and then to perform the PFE protocol using the procedure.

Crewmembers will also be trained on the Russian ergometer (Veloergometer) in Star City, Russia by Russian instructors at approximately L-12 months.

Schedule:

Duration:	Schedule:	Personnel Required:
1.5 hours	L-1 year CMS CEVIS Ops	Instructors/Crew
1.5 hours	L-150 CMS PFE Ops	Instructors/Crew CMO/Flight Surgeon
2 hours	L-6 months CMS OPS SKILLS	Instructors/CMO
60 min	L-180 Integrated Physical Fitness Assessment Training	Instructors/CMO/EXL

MEDB 4.1 Cycle Ergometer Test/Aerobic Functional Capacity

<table>
<tr><td rowspan="2">Ground Support Requirements Hardware/Software</td><td colspan="2">Preflight Hardware:</td><td colspan="2">Preflight Software:</td><td>Test Location:</td></tr>
<tr><td colspan="2">Veloergometer (Russian Training Only)
ISS Ergometer (CEVIS)
Station Support Computer
Metabolic Gas Analyzer
Consumables
BP/ECG
Heart Rate Monitor (HRM)
Rating of Perceived Exertion (RPE) Chart
PCMCIA Card or USB
Infrared USB Adapter (for downloading)</td><td colspan="2">CMS software application on SSC for BP/ECG
CEVIS Control Panel w/Windows Operating System
SSC Software For Metabolic Gas Analysis*
CMS software application on SSC for HRM
Polar Software</td><td>U.S. and Russia</td></tr>
<tr><td rowspan="4">Training Facilities</td><td>Minimum Room Dimensions:</td><td>Number of Electrical Outlets:</td><td>Temperature Requirements:</td><td>Special Lighting:</td></tr>
<tr><td>Approximately 20 ft. x 20 ft.</td><td>Two 120 VDC and one 110 VAC (USA)
Five 220 (Russia)</td><td>20 -25°C</td><td>N/A</td></tr>
<tr><td>Hot or Cold Running Water:</td><td>Privacy Requirements:</td><td colspan="2">Other:</td></tr>
<tr><td>Both</td><td>N/A</td><td colspan="2">N/A</td></tr>
<tr><td>Constraints/Special Requirements:</td><td colspan="4">Wear workout clothing (shorts, t-shirt, sneakers).
Test Termination Criteria: See page 7.</td></tr>
<tr><td>Launch Delay Requirements:</td><td colspan="4">Crewmembers will be required to participate in refresher training sessions if launch is delayed by more than 3 months.</td></tr>
<tr><td>Notes:</td><td colspan="4">N/A</td></tr>
</table>

3.4 Preflight Activities

TABLE 3.4: PREFLIGHT ACTIVITIES

<table>
<tr><td rowspan="4">Preflight Activity
Description:

Schedule:</td><td colspan="5">Cycle Exercise Test: Electrocardiogram and blood pressure measurements shall be performed at the end of 5 minutes of supine rest and three minutes of seated rest prior to the exercise portion of the test. ECG and metabolic gas analysis shall be conducted during the exercise portion of the testing. One of two cycle exercise protocols will be used for testing (either a “light” or “nominal” protocol). The choice of protocol used is primarily dependent on the crewmember’s body weight (light protocol is designed for those weighing < 65 kg), but the nominal protocol also may be used for an individual weighing < 65 kg who regularly performs cycle exercise training. See “Cycle Exercise Test Protocols” Table below for further specifics.</td></tr>
<tr><td>Duration:</td><td>Schedule:</td><td>Flexibility:</td><td>Blood Volume</td><td>Personnel Required:</td></tr>
<tr><td>Annual Test:</td><td>60 min</td><td>Annually</td><td>+/- 30 days</td><td>N/A</td><td>Lab personnel, Crewmember, Physician “on call” and within 10 min of facility (test to be performed during normal clinic hours)</td></tr>
<tr><td>Single Flow to Launch Schedule (Crewmember Assigned to Specific Mission):</td><td>60 min
60 min
60 min</td><td>L-21 to L-18 months
L-9 to L-6 months
L-3 to L-1 months*</td><td>+/- 30 days
+/- 30 days
+/- 30 days
Ideally L-1 month, flexibility is given due to launches in Russia. The closer to launch, the more accurate the exercise prescriptions derived from testing.</td><td>N/A</td><td>Lab personnel, Crewmember, Physician “on call” and within 10 min of facility (test to be performed during normal clinic hours)
*Prefer assigned crew surgeon</td></tr>
<tr><td rowspan="2">Ground Support Requirements Hardware/Software</td><td colspan="2">Preflight Hardware:</td><td colspan="2">Preflight Software:</td><td>Test Location:</td></tr>
<tr><td colspan="2">LODE Electronic Cycle Ergometer
Electrocardiographic System*
Metabolic Gas Analyzer*
Metabolic Gas Analyzer Accessories
Metabolic Gas Analyzer Consumables
Sphygmomanometer
RPE Chart</td><td colspan="2">Ergometer Software
Electrocardiographic Software*
Metabolic Gas Analysis Software*</td><td>U.S.</td></tr>
<tr><td rowspan="4">Testing Facilities</td><td>Minimum Room Dimensions:</td><td>Number of Electrical Outlets:</td><td colspan="2">Temperature Requirements:</td><td>Special Lighting:</td></tr>
<tr><td>Approximately 20 ft. x 20 ft.</td><td>Four 110V and one 220V</td><td colspan="2">20 -25°C</td><td>NA</td></tr>
<tr><td>Hot or Cold Running Water:</td><td>Privacy Requirements:</td><td colspan="3">Other:</td></tr>
<tr><td>Access to hot and cold running water is necessary.</td><td>Access to room must be controlled during testing.</td><td colspan="3">All monitoring personnel will be AED-qualified, and an AED will be present within the test facility.</td></tr>
</table>

Constraints/Special Requirements:	• No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing. • Wear workout clothing (shorts, t-shirt, sneakers). • No large meals 2 hrs prior to test. A light meal permitted up to 60 minutes before test. • Limit caffeine intake to one cup (8 oz) of regular coffee or equivalent 60 minutes before test. • No alcohol or nicotine 8 hrs prior to test. • Do not apply lotion to the torso on the day of testing (pretest). • Contraindications: previous musculoskeletal injury which would prevent cycle exercise to maximal levels. • No Neutral Buoyancy training 48 hours prior to test; prefer 72 hours. • A 12-lead ECG is required for all annual and single flow to launch testing. The system currently required is the GE CASE system which allows direct transmission of electrocardiographic data to a cardiologist for interpretation. Exception, a "frontal plane only" (6 lead) ECG recording for rhythm monitoring purposes is used for the test conducted in the L-3 to L-1 time-frame. • The metabolic gas analysis system required for annual testing and the L-21 to L-18 single flow to launch test is the Parvo Medics True One 2400 system. • The metabolic gas analysis system recommended the single flow to launch testing conducted at L-9 to L-6 months and L-3 to L-1 month is the system currently onboard ISS (the ESA/Damec Portable Pulmonary Function System). • MEDB 4.1 will not be conducted with the crewmembers within 72 hours of returning to Houston from overseas travel or within 48 hours of domestic travel unless approved by the Crew Surgeon. **Test Termination Criteria: See page 7.**
Launch Delay Requirements:	L-3 to L-1 data collection will be repeated if launch is delayed by more than 3 months.
Notes:	• A peak cycle exercise test performed within one year of the launch date may be substituted for the L-9 mo. test upon crew surgeon approval. • If review of the test data indicates that the crew member did not give a maximal effort, a test session shall be rescheduled as soon as practical. • After the L-3 to L-1 testing session, a set of cycle exercise protocols for on-orbit use must be transmitted to Astronaut Strength Conditioning and Rehabilitation personnel.
Data Delivery	• The 12-Lead ECG test data shall be transmitted to the cardiologist and the Picture Archive and Communication System (PACS) within 48 hours of testing (prefer immediately following). The PACS/Electronic Medical Record (EMR) will serve as the archive of final reports delivered to the flight surgeon. Raw ECG data will be archived in the GE CASE system. A preliminary report of test findings may be viewed directly by the crew surgeon via the PACS. Final reports with cardiologist interpretation will be posted to the EMR from PACS within 14 days following the test session. • Cycle exercise test data including the metabolic gas analysis data, will be analyzed by the discipline experts and a final report shall be posted to the Mission Medical Repository (MMR) within 14 days following the test session. The MMR will serve as the archive of the exercise test data. A preliminary report of test findings may be directly sent to the crew surgeon and ASCR personnel. • Cycle test data also will be shared with EVA experts to develop EVA pre-breathe reduction exercise protocols for pre-flight training

Peak Cycle Exercise Test Protocol

Nominal (Watts)	Light (Watts)	Stage Time (min)	Elapsed Time (min)
Seated Rest	Seated Rest	3:00	3:00
50	45	3:00	6:00
75	60	1:00	7:00
100	75	1:00	8:00
125	90	1:00	9:00
150	105	1:00	10:00
175	120	1:00	11:00
200	135	1:00	12:00
225	150	1:00	13:00
250	165	1:00	14:00
275	180	1:00	15:00
300	195	1:00	16:00
325	210	1:00	17:00
350	225	1:00	18:00
375	240	1:00	19:00
400	255	1:00	20:00
425	270	1:00	21:00
450	285	1:00	22:00
475	300	1:00	23:00

Note: Nominal Protocol is to be used for subjects weighing >65 kg. However, clinical discretion may be used in the assignment of protocols. For example, the Nominal Protocol would also be appropriate for a 62 kg lighter individuals who regularly perform cycle exercise. The pedaling speed for use during these tests is 75 rpm.

Cycle Exercise Test Termination Criteria

1. Onset of symptoms consistent with angina pectoris
2. Sustained ventricular tachycardia (defined as 7 or more sequential complexes)
3. Technical difficulties monitoring the ECG
4. Unusual or severe shortness of breath (inconsistent with level of effort)
5. Signs of poor perfusion, including pallor, cyanosis, or cold and clammy skin
6. Volitional fatigue

3.5 In-Flight Activities

TABLE 3.5.1: IN-FLIGHT ACTIVITIES

<table>
<tr><td>In-Flight Activity
Description:</td><td colspan="5">Cycle ErgometryTest:
A cycle ergometry test will be performed on the inflight cycle ergometer on flight day 14 then every 30 days of the mission. The test is also required for ISS crewmembers performing EVAs in the EMU.
Russian 3-lead ECG Gamma-1 Equipment or HRM can be used to measure heart rate per crew surgeon discretion.</td></tr>
<tr><td rowspan="3">Schedule:</td><td>Duration:</td><td>Schedule:</td><td>Flexibility:</td><td>Blood Volume:</td><td>Personnel Required:</td></tr>
<tr><td>90 min
90 min</td><td>FD 14 then every 30 days
Within 1 week of EVA</td><td>+/- 2 days
+/- 2 days</td><td>NA
NA</td><td>ISS Crewmember
ISS crewmembers who will perform EVAs in the EMU</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td>Procedures:</td><td colspan="5">2.2.775 Periodic Fitness Evaluation – Nominal Operations and 2.2.800 Periodic Fitness Evaluation – With CEVIS Contingency Controller</td></tr>
<tr><td>Constraints / Special Requirements:</td><td colspan="5">• Wear workout clothing (shorts, t-shirts, sneakers).
• No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing.
• Limit caffeine intake to 1 cup (8 oz) of regular coffee or equivalent 60 minutes before test.
• No large meals 2 hrs prior to test. A light meal is permitted up to 60 minutes before test.
• No alcohol, or nicotine 8 hrs prior to test
• Do not apply lotion to the torso on the day of testing (pretest).
• Contraindications: previous musculoskeletal injury.
Test Termination Criteria: See page 7.
Each crewmember will don a Heart Rate Monitor and BP/ECG (3-lead).</td></tr>
<tr><td>Photo / TV Requirements:</td><td colspan="5">Obtain video of the first PFE for each crewmember. 5 min setup, 5 min stow per session.</td></tr>
<tr><td>Cold Stowage Requirements:</td><td colspan="5">NA</td></tr>
<tr><td>Mission Extension Requirements:</td><td colspan="5">Continue nominal schedule as outlined in the description.</td></tr>
<tr><td>Landing Wave-Off Requirements:</td><td colspan="5">NA</td></tr>
<tr><td>Notes:</td><td colspan="5">In the event that the cycle ergometer is inoperable the Russian ergometer and/or Treadmill may be considered for use as contingency devices.</td></tr>
<tr><td>Data Delivery</td><td colspan="5">CEVIS, BP/ECG and HR monitor data will be downlinked and placed on the MEME FTP server for discipline expert analysis. Test results will be shared with ASCR for interpretation and recommendations. The discipline experts will deliver test results and final recommendations to the crew surgeon via the MMIS within 48 hours of receiving initial cycle exercise data.</td></tr>
</table>

In-Flight Activities, (cont.)

TABLE 3.5.2: IN-FLIGHT HARDWARE

Hardware/Software Name
Russian Ergometer (operational)
Russian Ergometer (transport)
ISS Ergometer
CEVIS Accessory Bag
Isolator Kit Assembly
On-Orbit Mounting Frame
IVIS Box, Blue
IVIS Box, Red
Station Support Computer Kit 1 USB
Blood Pressure / Electrocardiograph Monitor (BP/ECG) Kit
BP/ECG Resupply Kit
Heart Rate Monitor Kit

3.6 Postflight Activities

TABLE 3.6: POSTFLIGHT ACTIVITIES

<table>
<tr><td rowspan="3">Postflight Activity
Description:

Schedule:</td><td colspan="5">Cycle Exercise Test: Crewmembers will perform the same cycle exercise test protocol postflight as performed preflight.</td></tr>
<tr><td>Duration:</td><td>Schedule:</td><td>Flexibility:</td><td>Blood Volume:</td><td>Personnel Required:</td></tr>
<tr><td>60 min
60 min</td><td>R+ 1/14 days
R+ 20/60 days</td><td>+/- 2 days
+/- 4 days</td><td>NA</td><td>Lab personnel/ Crewmember
Crew surgeon physically present on R+5</td></tr>
<tr><td rowspan="2">Ground Support Requirements Hardware/Software</td><td colspan="3">Postflight Hardware:</td><td>Postflight Software:</td><td>Test Location:</td></tr>
<tr><td colspan="3">LODE Electronic Cycle Ergometer
Electrocardiographic System*
Metabolic Gas Analyzer*
Metabolic Gas Analyzer Accessories
Metabolic Gas Analyzer Consumables
Sphygmomanometer
RPE Chart</td><td>Ergometer Software
MGA Software</td><td>U.S.</td></tr>
<tr><td rowspan="4">Testing Facilities</td><td>Minimum Room Dimensions:</td><td>Number of Electrical Outlets:</td><td colspan="2">Temperature Requirements:</td><td>Special Lighting:</td></tr>
<tr><td>Approximately 20 ft. x 20 ft.</td><td>Four 110V and one 220V</td><td colspan="2">20 -25°C</td><td>NA</td></tr>
<tr><td>Hot or Cold Running Water:</td><td>Privacy Requirements:</td><td colspan="3">Other:</td></tr>
<tr><td>Access to hot and cold running water is necessary</td><td>Access to room must be controlled during testing.</td><td colspan="3">All monitoring personnel shall be AED qualified and an AED shall be present within the test facility. The crew surgeon must be present at the R+5 test. During the R+30 test the same “on call” restraints as preflight tests shall apply.</td></tr>
</table>

Constraints/Special Requirements:	• No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing. • Wear workout clothing (shorts, t-shirt, sneakers). • No large meals 2 hrs prior to test. A light meal permitted up to 60 minutes before test. • Limit caffeine intake to one cup (8 oz) of regular coffee or equivalent 60 minutes before test. • No alcohol, or nicotine 8 hrs prior to test • Do not apply lotion to the torso on the day of testing (pretest). • Contraindications: previous musculoskeletal injury which would prevent cycle exercise to maximal levels. • No Neutral Buoyancy training 48 hours prior to test; prefer 72 hours. • A "frontal plane only" (6 lead) ECG recording for rhythm monitoring purposes is required. • The metabolic gas analysis system used for post-flight testing shall be an identical make and model to that used for the L-3 to L-1 testing. • MEDB 4.1 will be not be conducted with the crewmembers within 72 hours of returning to Houston from overseas travel or within 48 hours of domestic travel unless approved by the Crew Surgeon. This requirement may be waived if the normal direct crew return to the U.S. is delayed. **Test Termination Criteria: See page 7.**
Early Destow / Early Return:	NA
Notes:	NA
Data Delivery	The 12-Lead ECG test data shall be transmitted to the cardiologist and the Picture Archive and Communication System (PACS) within 48 hours of testing (prefer immediately following). The PACS/Electronic Medical Record (EMR) will serve as the archive of final reports delivered to the flight surgeon. Raw ECG data will be archived in the GE CASE system. A preliminary report of test findings may be viewed directly by the crew surgeon via the PACS. Final reports with cardiologist interpretation will be posted to the EMR from PACS within 14 days following the test session.

3.7 Summary Schedule

TABLE 3.7: SUMMARY SCHEDULE

ACTIVITY	DURATION	SCHEDULE	FLEXIBILITY	PERSONNEL REQUIRED	CONSTRAINTS
Preflight Training					
Countermeasures Systems CEVIS Operations (CMS CEVIS Ops)	1.5 hr	L-1 year	+/- 5 days	Instructors/CMO	
Countermeasures Systems Periodic Fitness Evaluation (PFE) Operations (CMS PFE Ops)	1.5 hrs	L-150 days	+/- 5 days	Instructors/CMO	
CMS OPS SKILLS	2 hrs	L-6 months	+/- 5 days	Instructors/CMO	
Integrated Physical Fitness Assessment Training	60 min	L-180 days	+/- 5 days	Instructors/CMO/ EXL personnel	
Preflight					
Annual Cycle Test – Non Assigned Astronaut	60 min	Annually	+/- 30 days	Lab personnel/ Crewmember	See Note
Single Flow to Launch Crewmembers	60 min 60 min 60 min	L-21 to L-18 months L-9 to L-6 months L-3 to L-1 months	+/- 30 days	Lab personnel/ Crewmember Medical Monitor	See Note
In-Flight					
Cycle Ergometry Test	90 min	FD 14 and every 30 days thereafter	+/- 2 days	ISS Crewmember	See Note
	90 min	Within 1 week of EVA	+/- 2 days	ISS Crewmember	ISS crewmembers who will perform EVAs in the EMU
Postflight					
Cycle Ergometry Test	60 min 60 min	R+1/14 days R+20/60 days	+/- 2 days +/- 4 days	Lab personnel/ Crewmember Medical Monitor	See Note
Postflight Debrief					
No extra time	~R+30 d	As scheduled	N/A	ASCR/ Crewmember/Lab Personnel/Crew surgeon	Included as part of the Med Ops overall debrief

MEDB 4.1 Cycle Ergometer Test/Aerobic Functional Capacity

Note:

- No max exercise 24 hrs prior to testing; no regular exercise 8 hrs prior to testing.
- Wear workout clothing (shorts, t-shirt, sneakers).
- No large meals 2 hrs prior to test. A light meal permitted up to 60 minutes before test.
- Limit caffeine intake to one cup (8 oz) of regular coffee or equivalent 60 minutes before test.
- No alcohol, or nicotine 8 hrs prior to test
- Do not apply lotion to the torso on the day of testing (pretest).
- Contraindications: previous musculoskeletal injury which would prevent cycle exercise to maximal levels.
- No Neutral Buoyancy training 48 hours prior to test; prefer 72 hours.
- A "frontal plane only" (6 lead) ECG recording for rhythm monitoring purposes is required.
- The metabolic gas analysis system used for post-flight testing shall be an identical make and model to that used for the L-3 to L-1 testing.
- MEDB 4.1 will be not conducted with the crewmembers within 72 hours of returning from overseas travel or within 48 hours of domestic travel unless approved by the Crew Surgeon. This requirement may be waived if the normal direct crew return to the U.S. is delayed